



DEPARTMENT OF THE NAVY
NAVAL MEDICAL RESEARCH CENTER
503 ROBERT GRANT AVENUE
SILVER SPRING, MARYLAND 20910-7500

IN REPLY REFER TO:

NAVMEDRSCHCENINST 5721.1B

025

18 MAY 2011

NAVMEDRSCHCENTER INSTRUCTION 5721.1B

From: Commanding Officer, Naval Medical Research Center

Subj: COMMAND PUBLICATIONS PROGRAM

Ref: (a) DoD Directive 3216.2 dated 25 Mar 02
(b) SECNAVINST 5720.44B dated 1 Nov 05
(c) BUMEDINST 5721.3C dated 12 May 10
(d) BUMED Correspondence dated 4 Dec 09

Encl: (1) Request for Clearance for Authored Works Form
(CPP Form 1, V9, 05.2011)
(2) Request for Clearance for Authored Works Attachment 1
(CPP Form 2, V3, 05.2011)
(3) Endorsement of Previously Cleared Authored Work
(CPP Form 3, V2, 05.2011)
(4) NMRC Review & Endorsement Form
(CPP Form 4, V6, 05.2011)

1. Purpose. To promulgate procedures governing publication clearance process for authored works at the Naval Medical Research Center (NMRC) and its subordinate activities.

2. Cancellation. NAVMEDRSCHCENINST 5721.1A is hereby cancelled and superseded.

3. Background. Publications and presentations are governed by standards and norms detailed in references (a) through (d). According to reference (c), authored work is defined as "any written document or oral presentation, prepared in your professional capacity, intending to be published or presented to the general public. Additionally, "authored work" shall include any written document or oral presentation prepared in your personal capacity that contains information that may adversely affect national security, threaten the safety or privacy of U.S. Government personnel or their families, violate the privacy of citizens of the U.S., or be contrary to law. This includes any authored work that is to be transmitted via the Internet (i.e., blogs, podcasts, twitter, etc.), mass broadcast, or mass e-mail where the general public may be able to obtain the authored work." This includes any authored work that can be referenced or cited, such as journal articles, manuscripts, letters to the editor, case reports, published abstracts, book chapters and technical reports. Presentations consist of items for oral or visual presentation at a symposium or meeting.

4. Scope. The requirements of this instruction are applicable to all NMRC and Echelon 4 and 5 authors, directorates and departments. Additionally, when a Memorandum of Understanding (MOU), Memorandum of Agreement (MOA), Cooperative Research and Development Agreement (CRADA) or other research partner submits a publication for NMRC review as part of the terms of the agreement, the collaborating directorate will initiate clearance procedures if there is no current NMRC associated investigator.

5. Responsibilities.

a. Naval Medical Research Center.

(1) The author will:

(a) Submit enclosure (1) at least 31 working days (10 for NMRC and 21 for BUMED) prior to submission date.

(b) Provide a synopsis, enclosure (2), of the authored work.

(c) Include the required statement(s) (i.e., Navy disclaimer, human or animal research, source of funding, and copyright) in the submitted authored work.

(d) Ensure final copies of accepted and cleared presentations are submitted to ORA one week prior to the date of the presentation or meeting.

(e) Forward manuscripts to ORA upon publication.

(f) For authored works previously cleared for submission where the author wishes to make a minor change (i.e. submit to another Journal or domestic venue), submit the revised work using enclosure (3).

(2) The submitting directorate will:

(a) Conduct a substantive scientific and professional review.

(b) Ensure that the clearance request is complete.

(c) Ensure that the clearance request is submitted in a timely manner according to 5.a.(1)(a).

(3) The Office of Research Administration (ORA) will:

(a) Verify that the submitted publication clearance request is completed accurately.

(b) Ensure that the clearance request adheres to the regulations and policies for the protection of human subjects in research.

(c) Forward all clearance requests via the chain of command in a timely manner, using enclosure (4).

(d) Forward to the Bureau of Medicine and Surgery (BUMED) (M09B7) all clearance requests that require higher authority review and approval.

(e) Inform the author of the status of the submitted clearance request when the following occurs:

1. Changes or additional information is required prior to submitting via the chain of command.

2. The clearance request has been approved/disapproved by the Command.

3. The clearance request has been forwarded to BUMED (M09B7C) for higher review and approval.

4. The clearance request has been forwarded by BUMED (M09B7C) to higher authority (Department of Defense (DoD), the Secretary of the Navy (SECNAV) or the Chief of Naval Operations (CNO)) for review and approval.

5. The clearance request has been approved/disapproved by BUMED (M09B7C) or higher authority.

(4) Director, Research Services will:

(a) Perform a secondary review of the clearance request.

(b) Ensure that the clearance request adheres to the standards regarding the protection and use of animals in research.

(c) Acknowledge receipt and review of the request using enclosure (4).

(5) Legal and Technology Services Department through the Office of Research Technology and Application will:

(a) Ensure that the clearance request adheres to the standards regarding the protection and appropriate use of data/intellectual property and the standards regarding scientific misconduct.

(c) Determine if patent issues or potential patent issues are involved.

(d) Provide Command ethics and legal review.

(e) Acknowledge receipt and review of the request using enclosure (4).

(6) Public Affairs Officer (PAO) will:

(a) Conduct a review to determine any potential media interest.

(b) Determine if higher authority review is required.

(c) With delegated authority from the Commanding Officer, approve/disapprove clearance requests that do not require higher authority review.

(d) Acknowledge receipt and review of the request using enclosure (4).

(e) For authored works previously cleared for submission, where the author wishes to make a minor change, the PAO will review the request using enclosure (3).

b. NMRC Subordinate Echelon 4 and 5 Commands.

(1) Subordinate activity Commanding Officers/Officers-in-Charge will:

(a) Establish a publications program in accordance with references (a) through (d) and this instruction as applicable for the activity.

1. Use enclosure (1) to request clearance or ensure that local forms incorporate all of the required elements from enclosure (1).

2. Submit enclosure (2) and when applicable, enclosure (3), with the local clearance request document.

(b) Forward a copy of all locally approved abstracts and manuscripts to NMRC via the chain of command.

(c) When higher authority review is required, all Echelon 4 and 5 activities will forward clearance requests to BUMED (M09B7C) or higher authority via the chain of command for endorsement.

6. Navy - Funded Research.

a. For programs where NMRC serves as administrator of funds to non-governmental researchers, institutions or programs (i.e., Advanced Medical Development programs, etc.), materials do not require higher level clearance unless 1) it addresses plans, policies, programs or operations of the DoD or the U.S. government, or 2) it is potentially or inherently controversial or likely to receive media coverage or publicity.

b. The material must still be cleared locally by the Command PAO. The point of contact should receive a copy of the authored work to review prior to its submission for publication to ensure that the material is cleared locally by the Command and the U.S. Government's interests are protected. The funding source statement should be included and the outside entity should be encouraged to include the disclaimer statement as provided in reference (c). Examples of such materials include peer reviewed publications or presentations before professional communities or organizations that do NOT contain subject matter described in 6a above.

7. Forms. An electronic version of the required clearance forms provided in enclosures (1) through (4) are available on the NMRC Internet and Intranet sites and may be reproduced locally.


R. L. HABERBERGER, JR.

Distribution:
List(s) A, B, C and D



ORA Use Only

File No.

Request for Clearance for Authored Works

Instructions: Pursuant to NAVMEDRSCHCENINST 5721.1B, NMRC must prospectively clear all publications and presentations. NMRC authors should:

1. Complete Parts A-E of this form.
2. Route through Directorate for chain of command and scientific review and signature.
3. Submit to ORA for processing and routing for Command review.

All information must be complete; incomplete answers may result in delay. Please allow NMRC at least 10 working days for its review. Please note that BUMED requires 21 working days for its review and an additional 21 days may be required for items requiring further review by a higher authority (e.g., DoD, SECNAV or CNO).

Part A – Background Information

1. Directorate/Dept:

2. Title of Publication or Presentation:

3. Author(s): *(List authors starting with primary author)*

☐ Check if authors number more than listed below.

Author(s) Name	Institutional Affiliation	Role in Research

4. Work Unit Number (only one work unit/project allowed):

If no WUN, please:

a. Provide source of support:

b. Check one of the following:

- ☐ Work was done prior to employment at NMRC
- ☐ Work was done as a consultation for another institute while employed by/stationed at NMRC
- ☐ Other - please explain:

5. Activity involves *(select all that apply)*:

☐ Human Subject Research Protocol No.:

☐ Project No.:

Projects that have been reviewed by the IRB Chair and determined to not meet the definition of human subjects' research will have a "project number." Please refer to the form entitled, "Determination of Human Use Research Status," for further information.

☐ Animal Use Research Protocol No.:

7. Is activity supported by a Grant, CRADA, MTA, NDA or other agreement: ☐ Yes ☐ No

If yes, please provide the following:

- Grant/Agreement Type and No.:
- Grant/Agreement Sponsor Name:
- Grant/Agreement Title:
- Contractor/Collaborator/Recipient Name:
- Has the non-government party been given advance notice of publication required by the agreement prior to submission? ☐ Yes ☐ No

8. Relevance of manuscript or presentation to operational medicine/Navy medicine:

9. Summary of media sensitive subject matter:

Part B – Purpose/Forum

1. Journals *(please attach copies of submission)*

Journal title:

- ☐ Manuscript ☐ Letter to the Editor ☐ Case Report ☐ Other:
☐ Domestic ☐ Foreign *(Country)*

2. Meeting/Conference *(please attach copies of submissions)*

a. Name:

b. Dates of Meeting:

c. Location:

- ☐ Abstract for oral presentation/briefing (submission deadline date)
☐ Abstract for poster/exhibit (submission deadline date)
Please submit an electronic copy of poster one week prior to departure.
☐ Keynote presentation (submission deadline date)
☐ Other, please explain:

3. Other *(please attach copies of submissions)*

- ☐ Book chapter, provide title of book, editor(s), publisher:
☐ Technical report

Part C – Required Disclaimers and Acknowledgments

Note on Abstracts: Because abstracts are usually limited to a specific word count and/or are used to determine whether the work will be accepted for publication or presentation, the required Navy disclaimers, acknowledgement of support, human and animal involvement statements are generally not included in the abstract. However, these statements should be included in the actual publication and/or presentation (e.g., posters, slides, etc.)

1. Disclaimer:

Publications and presentations for which an author claims Navy affiliation, the disclaimer provided below should be included. Further, manuscripts and professional articles completed in an official capacity or funded by the government shall identify the author with complete name, military grade, title and command.

The views expressed in this article are those of the author and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, nor the U.S. Government.

☐ **Yes, page:**

2. Source of support (e.g., WUN):

All publications and presentations must disclose all sources of Navy funding, for example:

This work was supported by funded by work unit number xxxx.

☐ **Yes, page:**

☐ **No, please explain:**

3. Human Research Protections/IRB statement:

All publications and presentations concerning research involving the use of human subjects must contain the following statement:

The study protocol was approved by the Naval Medical Research Center Institutional Review Board in compliance with all applicable Federal regulations governing the protection of human subjects.

☐ **Yes, page:**

☐ **No. If human research protocol number provided above please explain:**

4. Animal Care and Use statement:

All publications and presentations concerning research involving animals must contain such a statement.

The experiments reported herein were conducted in compliance with the Animal Welfare Act and in accordance with the principles set forth in the "Guide for the Care and Use of Laboratory Animals," Institute of Laboratory Animals Resources, National Research Council, National Academy Press, 1996.

☐ **Yes, page:**

☐ **No. If animal research protocol number provided above please explain:**

5. Copyright statement:

The copyright statement must be attached to all government work when submitted to civilian media for publication.

I am a military service member (or employee of the U.S. Government). This work was prepared as part of my official duties. Title 17 U.S.C. §105 provides that 'Copyright protection under this title is not available for any work of the United States Government.' Title 17 U.S.C. §101 defines a U.S. Government work as a work prepared by a military service member or employee of the U.S. Government as part of that person's official duties.

☐ **Yes, page:**

Part D – Author Attestation & OIC/Directorate Review

AUTHOR: I attest that the above information is correct and accurate to the best of my knowledge.

Signature: _____

Date: _____

Print Name:

Rank:

Print Title:

DEPARTMENT HEAD:

Signature: _____

Date: _____

Print Name:

LOCAL OIC/DIRECTORATE: This submission has received scientific review.

Signature: _____

Date: _____

Print Name:



Request for Clearance for Authored Works Attachment 1

ORA Use Only:

File No.

Submitting
Command:

Author's Command:

Part A – NMSC PAO Synopsis

Instructions: Investigators complete this form and submit as an attached Word Document. This synopsis should be prepared in non-scientific terms and consistent with Part B of the Publication Clearance Request Form (CPP- Form 1).

The text provided below is to be used as an example only. Authors should highlight the gray areas and press the backspace button on your keyboard. The text provided below will disappear and authors will be able to input their own information here as appropriate.

- 1. Publication Title:** Example: Morphine Use after Injury Protects Against PTSD Onset: Findings From the Navy Marine Corps Combat Trauma Registry Deployment Health Database
- 2. Purpose/Forum** Example: This is an article that will be submitted to JAMA for an upcoming issue yet to be determined.
- 3. Background/Synopsis:** Example: This report's objective was to examine the effect of morphine use during early resuscitation and trauma care on PTSD onset in injured military personnel. These results provide new evidence that morphine or other compounds may protect.
- 4 Results:** Example: These finding have important implications for future pharmacological interventions to reduce PTSD incidence after serious injury and exposure to traumatic events.
- 5. Conclusions:** Example: The have the potential to wield a profound impact on PTSD prevention and provide a foundation for continuing to improve 21st century trauma care.
- 6. Sensitive areas/media interest:**



Endorsement of Previously Cleared Authored Work

ORA Use Only**File No.****Author's Command:**

Instructions: This form may be used for processing previously cleared materials that are being submitted to a new journal **only if** the authored work has not been significantly altered from the previously cleared version.

Part A – Background Information

1. **Directorate/Dept:**
2. **Title of previously cleared authored work:**
3. **ORA File No. of Previously Cleared Version:**

☐ Copy of previous approval attached

Part B – Specific Changes to Authored Work

1. **Title Change** (please provide the new title of the authored work):
2. **Journal / Venue Change:**
Journal / Venue title:
Date(s) & Location:
3. **Author(s) Change(s):** (*print name(s)*):

☐ Check if list of authors has NOT changed from previous version.

Part C – Author Attestation

AUTHOR: I attest that the above information is correct and accurate to the best of my knowledge and that no significant changes have been made to the previously cleared submission.

Signature: _____
Name: _____

Date: _____

Part D – Command Review

PAO/COMMAND:

- ☐ **Expedited clearance** (no significant changes from previously cleared submission)
- ☐ **Return to author to submit using CCP Form 1** (See comments below)
- ☐ **Requires more information to make a determination** (See comments below)
- ☐ **Requires higher level review** (See comments below)

Comments or Concerns:

Signature: _____

Date: _____

Doris Ryan
NMRC PAO

Email Address: Doris.Ryan@med.navy.mil

Telephone: 301-319-9378

**NMRC Review & Endorsement Form****ORA Use Only**

File No. _____

Submitting Command: _____

Author's Command: _____

Part F – Command Review**OFFICE OF RESEARCH ADMINISTRATION:**

Signature: _____

Terri R. Brantley, Head, ORA

Date: _____

RESEARCH SERVICES DIRECTORATE:

Signature: _____

Adam E. McKee, DVM, Director, RSD

Date: _____

LEGAL AND TECHNOLOGY SERVICES DEPARTMENT:

Signature: _____

Roxanne Charles, ORTA

Date: _____

Signature: _____

Albert M. Churilla, PhD, JD, Patent Attorney

Date: _____

PAO/COMMAND:**Check all of the following items that apply to this publication or presentation:**☐ Forwarded from submitting command **for information only**

If a "yes" option is selected, higher review is required pursuant to BUMEDINST 5721.3C

Yes**No**☐☐☐☐☐☐☐☐☐☐☐☐

Non-human primates, cats, dogs or marine mammals

International Media

Controversial or sensitive

Potential media interest

Addresses government policy or findings more appropriately released by the Seat of Gov't.

Special Research Topic (e.g., Persian Gulf, Women's Issues, PTSD, etc.)

☐ **Cleared** (select if review by higher authority not required)☐ **Cleared at NMRC Only – Requires Higher Review & Clearance**

Signature: _____

Doris Ryan
NMRC PAO

Date: _____

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